K071717

SHIMADZU
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Medical Systems Division,
Quality Assurance Department

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January 31, 2007

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

JUL - 5 2007

Re: Abbreviated Premarket Notification 510(k) Submission

To Whom It May Concern:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act, Shimadzu Corporation is hereby submitting this Premarket notification prior to marketing the GE OEC Altitude SYSTEM in the United States.

DEVICE CLASSIFICATION:	Class II by CFR 892.1600
CLASSIFICATION PANEL:	Radiology
CLASSIFICATION NAME(S):	Angiographic X-ray System
PRODUCT CODE:	90IZI
COMMON NAME:	GE OEC Altitude
PROPRIETARY NAME:	Shimadzu Corporation
PREDICATE DEVICE:	Shimadzu Angiosigma NEO which consists of MH-100 (K943545) and DAR-2400-15B/30B (K955395).

The Official Contact is:

Mr. Akira Shigeyasu
Manager, Quality Assurance Department
Medical Systems Division
Shimadzu Corporation
1, Nishinokyo-Kuwabaracho
Nakagyo-ku, Kyoto 604-8511, Japan
Phone: +81-75-823-1307 / Fax: +81-75-823-1377
e-mail: sigeyasu@shimadzu.co.jp

The owner is located at:

Shimadzu Corporation
1,Nishinokyo-Kuwabaracho, Nakagyo-ku
Kyoto 604-8511, Japan

The manufacturing facility: Shimadzu Corporation

Please direct any additional questions or requests for information to our official contact.

Respectfully,

510(K) Notification Submission, GE OEC Altitude

Abbreviated 510K

Date: JAN. 16. , 2007
Our Reference: ZCBC06035

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

Re: Abbreviated 510(k) Notification
Angiographic X-ray System
GE OEC Altitude

Dear Sir or Madam:

This submission is being made in compliance with Section 510(k) of the Food, Drug and Cosmetic Act as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990 and the Food, Drug administration Modernization Act of 1997, and the Office of Device Evaluation guidance for Abbreviated 510(K) requirement for Digital Radiography System. The enclosed information is being submitted for our Angiographic X-ray System, GE OEC Altitude. Two copies of this Premarket Notification are being submitted in accordance with 21 CFR 807.

The purpose of this submission is to notify FDA , in accordance with the 510(K) provisions of the Act, of our intent to introduce this modified device.

A Table of Contents for the submission is located immediately following this letter. Should you have any questions or require additional information, please feel free to contact:

Thank you for your attention to this matter.
Sincerely yours,

Akira Shigeyasu

Akira Shigeyasu
Manager, Quality Assurance
Medical Systems Division
Shimadzu Corporation
Kyoto Japan

Technical Responsibilities:
cc. O.Sasaki

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL - 5 2007

Shimadzu Corporation
% Mr. Tamas Borsai
Division Manager, Medical Division
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K071717
Trade/Device Name: GE OEC Altitude
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: June 20, 2007
Received: June 22, 2007

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION XIII: INDICATIONS FOR USE

510(k) Number (if known): K071717

Device Name: GE OEC Altitude

Indications for use:

/ This device is intended to be used for generating fluoroscopic images of human anatomy for the diagnostic, surgical and interventional angiography and cardiology procedures of circulatory vascular system.

/ This device is operated and used by the physicians, X-ray technologist and radiologists.

/ This device can be used in conjunction with a mobile or fixed surgical table.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071717